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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/693,663

10/24/2003

Gene DiPoto

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EXAMINER

SWIGER III, JAMES L

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

08/04/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/693,663	<b>Applicant(s)</b> DIPOTO, GENE	
	<b>Examiner</b> JAMES L. SWIGER III	<b>Art Unit</b> 3733	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/5/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-12, 14-18 and 23-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cornwall et al. (US Patent 6,485,518) in view of Davison (US Patent 6,530,926).

Cornwall et al. teaches an intervertebral support and fusion system that allows for transfacet fixation using fasteners (30a and 30b) through one vertebrae to another and where other vertebrae may be adjacent to the surgical site. See Cols. 1 and 2 and also see Col. 3, lines 40-52). It is noted that the method of Cornwall et al. prefers a minimally invasive method (Col. 2, lines 18-21) and teaches that a single-cannula approach is possible in the spirit of a minimally-invasive, percutaneous procedure. It is further noted that Cornwall et al. also teaches the step of positioning at a preferred angle, considered inclining, at a preferred angle in performing a percutaneous and posteriolateral procedure. Cornwall et al. also teach the delivering of a first fastener to the surgical location, and also advancing the screw from a first vertebra and into a second vertebra.

Cornwall et al. teaches the claimed device except for the specific use of inserting into a patient an access device wherein said access device has a different diameter at a

distal end and has two configurations and also the step of inserting multiple fasteners. Modification of Cornwall et al to use the device of Davison allows improved access in performing the spinal surgery, yielding more space in the surgical area.

Davison teaches a percutaneous access device and cannula that is inserted into a patient (Fig. 5, 10, and Col. 2, lines 58-63), and wherein the access device has a first and second configuration (Col. 3, lines 3-39) and, with regards to claims 8-13 and 23, multiple fasteners can be inserted through the cannula to secure vertebrae. Davison teaches that multiple fasteners may be inserted (see Col. 13, lines 15-25, and Abstract). Additionally, in use of the device, the screws 30a and 30b are slightly angled to perform transfacet fixation.

Additionally, a substantially perpendicular plane with respect to the spine, denoted by the dotted line in Fig. 1 of Cornwall et al. must be crossed by the minimally-invasive cannula to complete the procedure for both screws. It is noted that the term "crossing" is not interpreted as the same thing as inclining. The plane represented in the drawing is a visual landmark and as noted previously, the cannula is inclined to insert a bone fastener with respect to this point. Thus, Davis teaches the step, of the device moving from a plane generally perpendicular to the spine of the patient at an established angle. It is an "angled approach." The cannula may be slightly (ie. substantially perpendicular) angled to complete the procedure and deliver the screws accordingly.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the method of Cornwall et al.

having/using the access device as taught by Davison to have improved access to the spinal area with a first and second configuration at an end for adjoining and securing vertebrae and also for inserting multiple screws in the vertebral area.

Claims 5 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Cornwall et al. '518 and Davison '926 as applied to claims 1 and 8, respectively above, and further in view of Neubardt (US Patent 5,196,015). The combination of Cornwall et al. '518 and Davison '926 disclose the claimed method except for the step of scoring the surgical location prior to delivering the fastener through the bone. Neubardt discloses an indirect scoring of the area that is performed by placing the tool to the area and verifying the mark of the tool tip by indicia located on the tool shaft. (Col. 5, lines 10-16). In this way the location is marked before the fastener or securing device is delivered. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate into the method of the combination of Cornwall et al. '518 and Davison '926 with the step of scoring and marking the area of interest for securing the fasteners in view of Neubardt to provide accurate fixation in a minimal access procedure.

Claims 19-20 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Cornwall et al. '518 and Davison '926. The combination of Cornwall et al. '518 and Davison '926 discloses the claimed invention except for a "generally perpendicular angle being between 10 and 45 degrees, or at least less than 60." It would have been obvious to one having ordinary skill in the

Art Unit: 3733

art at the time the invention was made to make a range of angle being between 10 and 45 degrees, or at least less than 60, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art, especially for access the spine posteriorly through a device. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

### ***Response to Arguments***

Applicant's arguments filed 9/28/2007 have been fully considered but they are not considered persuasive. It is noted that Cornwall et al. teaches that a single-cannula approach may be used. See above rejection.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER III whose telephone number is (571)272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L SWIGER/  
Examiner, Art Unit 3733

**/Eduardo C. Robert/**

**Supervisory Patent Examiner, Art Unit 3733**